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SLU 4538
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Robert B. Belshe et al.
Serial No.: 09/785,764
Art Unit: 1648
Confirmation Number: 2975
Filed: February 16, 2001
For: TEMPERATURE-SENSITIVE AND COLD-ADAPTED HUMAN PARAINFLUENZA
VIRUS TYPE 2 (HPIV-2) AND VACCINES BASED ON SUCH VIRUS
Examiner: Laurie A. Scheiner

August 17, 2004

REQUEST FOR RECONSIDERATION OF THE PATENT TERM ADJUSTMENT
PURSUANT TO 37 CFR 1.705

TO THE COMMISSIONER OF PATENTS,
SIR:

In response to the Issue Notification dated May 18, 2004, in the above-referenced patent application, applicants respectfully request reconsideration of the patent term adjustment determination. Pursuant to 37 CFR § 1.705(b) and/or (d), applicants submit the following statement of facts in support of this request for reconsideration.

The application was filed on February 16, 2001. The first Office action on the merits was mailed on July 3, 2001, which is within the fourteen (14) month period for the mailing of a first office action on the merits. The response to the first Office action was filed on October 3, 2001, which is within the three (3) month shortened statutory period for response. The second Office action was mailed on August 18, 2003, which is five-hundred sixty-one (561) days after the four (4) month period for reply by the Office. The response to the second Office action was filed on December 18, 2003, which is thirty

(30) days after the three (3) month shortened statutory period for response. The Notice of Allowance was mailed May 18, 2004, which is thirty (30) days after the four (4) month period for reply by the Office, and indicated that the subject application was entitled to a patent term adjustment of zero (0) days.

Based upon the above-recited facts, the delay on the part of the Office was five-hundred ninety-one (591) days. The delay on the part of applicants was thirty (30) days. The result is a patent term extension of five-hundred sixty-one (561) days.

Based upon a review of the Patent Application Information Retrieval (PAIR) database regarding the subject application, it appears that the Office inadvertently failed to record applicants' October 3, 2001, response to the first office action.¹ Instead, that response was not recorded by the Office until August 15, 2003. Accordingly, this incorrectly resulted in applicants being inadvertently charged with six-hundred eighty-one days (681) of delay (a term represented by the period of October 3, 2001 (three (3) months after the mailing of the first Office action) to August 15, 2003 (the incorrect recordation date of applicants' October 3, 2001, response)).

Moreover, this failed to credit applicants with the Office's delay. Specifically, applicants should have been credited with five-hundred sixty-one (561) days of term extension, this term being computed from February 3, 2002 (the end of the four (4) month period for reply by the Office to

¹ Copies of (1) the October 3, 2001, response, (2) the Express Mail Label from the envelope containing the response, and (3) the return postcard that accompanied the response and that is stamped as having been received by the Office of Initial Patent Examination (OIPE) on October 3, 2001, are enclosed herewith.

applicants' October 3, 2001, response) to August 18, 2003 (the date on which the Office's reply was mailed).

Accordingly, applicants believe that the above-referenced reduction of six hundred eighty-one (681) days should be removed from the patent term adjustment calculation. Moreover, applicants believe that the patent term should be increased by (561) days (representing the period of February 3, 2002 (the end of the four (4) month period for reply by the Office to applicants' October 3, 2001, response) to August 18, 2003 (the date on which the Office's reply was mailed)). This correction should bring the total patent term adjustment to 561 days. Applicants respectfully request a correction in the patent term adjustment to reflect the same.

A terminal disclaimer was not filed in this case.

The Commissioner is hereby authorized to charge the \$200.00 fee under 37 CFR § 1.18(e) to deposit account No. 19-1345.

Respectfully submitted,



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*Enclosures

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U 4538
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of R. Belshe et al.

Art Unit 1648

Serial No. 09/785,764

Filed February 16, 2001

Confirmation No. 2975

For TEMPERATURE-SENSITIVE AND COLD-ADAPTED HUMAN PARAINFLUENZA
VIRUS TYPE 2 (HPIV-2) AND VACCINES BASED ON SUCH VIRUS

Examiner L. Scheiner

October 3, 2001

AMENDMENT A AND RESPONSE

TO THE ASSISTANT COMMISSIONER FOR PATENTS,

SIR:

In response to the Office action of 3 July 2001 please
consider the following remarks and enter the following
amendments:

IN THE CLAIMS

Substitute claim 4 as follows:

4. (once amended) The isolated, attenuated viral strain
of claim 1 which is selected from the group of viral strains
consisting of those designated C3464, C3490, C3605, and subclones
or progeny of any of the aforementioned strains.

Please cancel claims 5, 15 and 22.

EL910280724US

REMARKS

Claims 1-4, 6-14, and 16-21 are currently pending in the application.

The amendment to claim 4 is supported by the specification and does not add new matter.¹

In view of the above, accordingly, claim 4 has been amended solely for the purpose of prosecuting the amended claim in this application. This amendment better encompasses the full breadth of certain aspects of the present invention, notwithstanding Applicants' belief that the original claim would have been allowable.

I. 35 U.S.C. 112, First Paragraph Rejection

Reconsideration is requested of the rejection of claims 4, 12-14, and 21 under 35 U.S.C. 112, first paragraph. In support of this rejection, the Office has asserted that these claims are not enabled because they are directed toward novel viral strains that are not obtainable by a repeatable method. The Office also notes that the enablement requirement may be satisfied by a deposit of the claimed viral strains.

Claim 4, as amended, is now directed toward only viral strains that have been deposited with the ATCC as indicated in the specification.² Claims 12-14, and 21, which are directed toward vaccines and methods employing the viral strain of claim 4, are also now only directed toward the use of viral strains that have been deposited. Accordingly, it is hereby certified that viral strains C3464 (ATCC Accession No. PTA-1471), C3490 (ATCC Accession No. PTA-1473), and C3605 (ATCC Accession No. PTA-1472), as set forth in claim 4, have been deposited under the Budapest Treaty and these strains will be irrevocably and without condition or restriction be released to the public upon the issuance of a patent.

¹See page 7, lines 1-5 of the Specification.

²Enclosed is a copy of the ATCC deposit certificate evidencing the deposit of the claimed viral strains.

In view of the claim amendments and the deposit of all viral strains claimed, the basis for this rejection has been removed.

II. 35 U.S.C. 102(e) Rejection

Reconsideration is requested of the rejection of claims 1 and 18 under 35 U.S.C. 102(e) in view of Cates.³

Claim 1 is directed toward an isolated, **attenuated** viral strain of human parainfluenza virus 2 and claim 18 is directed toward a method of inducing an immune response employing the isolated, **attenuated** viral strain of claim 1.

Cates, on the other hand, generally discloses hemagglutinin-neuraminidase (HN) and fusion (F) **glycoproteins** isolated and purified from **non-attenuated** parainfluenza viruses types 1, 2, and 3. Additionally, Cates discloses methods and vaccines employing these glycoproteins.

Claims 1 and 18, accordingly, are not anticipated by the Cates disclosure. The Office, however, in support of its rejection asserts that "Cates et al. teach a HPIV-2 attenuated strain (isolated HN and F glycoproteins)."⁴ This assertion is not correct. Nowhere does Cates disclose attenuated HPIV-2 strains. Cates merely discloses, as stated above, the isolation of two **glycoproteins** from **dead, non-attenuated** viral strains. Claims 1 and 18, on the other hand, are directed toward **attenuated** viral strains. "Attenuated" as generally known in the art and as defined in the specification, is a mutant viral strain that has been selected phenotypically for cold adaptation and temperature sensitivity relative to wild type strains.⁵ Importantly, the viral strains claimed in the present invention are **alive** and are not isolated proteins from non-attenuated viral strains, as disclosed in Cates.

³Cates et al., U.S. Patent No. 6,165,774.

⁴See Paper 5, at page 3.

⁵See page 4, lines 1-10 of the Specification.

Because the cited art does not disclose each and every element of the invention defined by claims 1 and 18, the rejection of these claims on the basis of anticipation is not proper. Accordingly, Applicants respectfully traverse this basis of rejection and request its reconsideration and withdrawal.

II. Conclusion

In light of the foregoing, Applicants request entry of claim amendments, withdrawal of claim rejections, and solicit an allowance of the claims. The Examiner is invited to contact the undersigned attorney should any issue remain unsolved.

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 4:

4. (once amended) The isolated, attenuated viral strain of claim 1 which is selected from the group of viral strains consisting of those designated [C3396,] C3464, C3490, [C3457,] [C3440,] C3605 [C3444], and subclones or progeny of any of the aforementioned strains.

Claim 5:

Canceled.

Claim 15:

Canceled.

Claim 22:

Canceled.

It is believed that no fee is required. If, however, there are any fees associated with this Amendment A and Response, the Commissioner is hereby authorized to charge Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in cursive script, reading "Kathryn J. Doty".

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Express Mail No.: EL910280724US

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

St. Louis University
Attn: Robert O. Webster, Ph.D.
3556 Caroline, Room 110
St. Louis, MO 63104

Deposited on Behalf of: St. Louis University, Technology Transfer Office, St. Louis
University School of Medicine

Identification Reference by Depositor:

Human Parainfluenza virus type 2, Clone 3464, Pool 619, PIV2,
C3464, CP50, EPP2, SLU 7255
Human Parainfluenza virus type 2 Clone 3605 Pool 620, PIV2,
C3605, CP47, SLU 7255
Human Parainfluenza virus type 2 Clone 3490 Pool 621, PIV2,
C3490, cp63, SLU 7255
Human Parainfluenza virus type 2 WILD TYPE, Pool 622, PIV2,
wild type, SLU 7255

Patent Deposit Designation

PTA-1471
PTA-1472
PTA-1473
PTA-1474

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above.
The deposits were received March 9, 2000 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: ☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

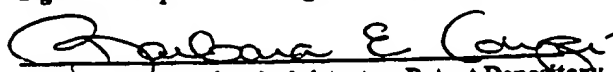
If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 21, 2000. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:


Barbara E. Coupé, Administrator, Patent Depository

Date: June 22, 2000

cc: Senninger, Powers, Leavitt & Roedel (Ref. Docket SLU 4505)

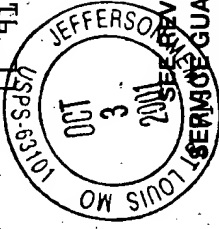


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File SLU 4538Client Name St. Louis University Attorney KJD/rleInventor(s) or Mark R. Belshé et al.Serial No. 09/785,764

The following has been received by the U.S. Patent and Trademark Office on the date stamped hereon: Patent/Reg. No. _____

☒ Amendment A and Response☐ Preliminary Amendment☐ Response to Missing Parts☐ Assignment and Cover Sheet☐ _____ Brief☐ Check \$ _____☐ Letter to Commissioner☐ CPA Request Transmittal☐ Maintenance Fee☐ Section _____ Declaration☒ Other Copy of ATCC deposit certificate☐ Other

Express Mail No.:

EL910280724US☐ Fee Transmittal Form☐ Combined Declaration/Power of Attorney☐ Notice of Appeal☐ Status Inquiry☐ IDS, PTO-1449, _____ References☐ _____ Sheet(s) _____ of Drawing(s)☐ Letter to Official Draftsman☐ Issue Fee/PTO-85b/Certificate of Mailing☐ Statement of Use☐ Extension of Time to Oppose